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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

EILEEN PEVIANI, on behalf of herself and all others similarly situated,

Plaintiff,

v.

NATURAL BALANCE INC.,

Defendant.

Case No: 3:10-cv-2451 AJB (BGS)

Pleading Type: Class Action

PLAINTIFF'S REPLY IN SUPPORT OF HER MOTIONS FOR CLASS CERTIFICATION & PRELIMINARY INJUNCTION

Judge: The Honorable Anthony J. Battaglia
Date: April 29, 2011
Time: 1:30 p.m.
Location: Courtroom 12

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INTRODUCTION

Plaintiff respectfully submits this Reply Memorandum in support of her Motions for Preliminary Injunction and Class Certification (Dkt. Nos. 11, 13).[1]

In her opening briefs, Plaintiff laid out the cases, with support and detailed analysis, for why the Court should issue a preliminary injunction and certify a class. NBI's oppositions do little to refute Plaintiff's opening arguments, instead confusing different standards, invoking irrelevant or inapposite arguments, re-arguing issues that have already been decided, and relying largely on an improperly-submitted legal argument drawing conclusions contrary to the FDA's own actions and explicit, codified regulation.

With respect to her Motion for Class Certification, Plaintiff has demonstrated each element of Rule 23 is met, and that certification under either Rule 23(b)(2) or 23(b)(3) is proper. NBI's only real argument is that Plaintiff is supposedly an improper class representative because she is a woman who purchased a men's product for her husband and never used it herself. But NBI's focus on Plaintiff's use is misplaced where her injury was in its purchase.

With respect to Plaintiff's Motion for Preliminary Injunction, NBI argues injunction should not issue because Plaintiff supposedly seeks to apply the "wrong" regulations to NBI's conduct. NBI claims Cobra Sexual Energy is not a drug despite labeling statements suggesting the product's use in the treatment of impotence, erectile dysfunction, or prostate dysfunction—the hallmark of a drug. NBI instead urges that Cobra Sexual Energy is a dietary supplement.

As NBI admits, "the regulatory classification of a product under the [FDCA] is determined by its intended use, as evidenced primarily by its labeling." (PI Opp. at 9.) While this action challenges specific statements appearing on Cobra Sexual Energy's packaging, when determining whether an article is properly classified as a drug or dietary supplement, the FDA examines the entirety of its labeling, including internet advertising. *See generally* 21 C.F.R. §

[1] NBI's two Oppositions (Dkt. Nos. 26-27) duplicate large sections of argument verbatim and rely on identical declarations and exhibits. In the interest of brevity, Plaintiff confines her Reply in Support of both Motions to this single submission.

201.128 (intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution).

The specific statements on Cobra Sexual Energy's packaging that Plaintiff challenges suggest the product is intended for use in the treatment of impotence, erectile dysfunction, or prostate dysfunction. As demonstrated below, the FDA has consistently held similar statements render similar products drugs under 21 U.S.C. § 321(g)(1).

But even if Cobra Sexual Energy's packaging were insufficient to establish that the product is a drug under the FDCA, its web advertising makes this absolutely clear. Those statements include claims that Cobra Sexual Energy has an acute effect on users ("take two capsules one hour prior to romantic activity"), that it is useful in treating the symptoms of impotence ("improves blood flow to the sex organs"), that a substance in the product "has been used in a popular prescription drug for impotence," that another substance in it is known as "potency wood," and more. The FDA has consistently held similar direct and indirect references to the treatment of impotence, erectile dysfunction or prostate dysfunction render an article a drug.

NBI's remaining arguments are without merit. For example, NBI has failed to refute Plaintiff's well-supported assertions of irreparable harm, especially when considering the lowered standard for showing irreparable harm on the "sliding scale" test where success on the merits is so likely. (*See* PI Mot. at 7-8.) Accordingly, Plaintiffs Motions should be granted.

FACTS

NBI sells Cobra Sexual Energy wholesale and—contrary to the representation of its Executive Vice President and Chief Operating Officer for the last 17 years (*see* Hinrichs Dec., Dkt. No. 26-1 and 27-1, ¶ 4)—directly to consumers. (*See* Declaration of Jack Fitzgerald, dated April 19, 2011 ("Fitzgerald Dec.") ¶¶ 2-7 & Exs. A-C.)

NBI advertises Cobra Sexual Energy on the internet, both on its own website and through information it provides to third-party retailers, distributors and sellers, who relay that information to consumers. The advertising for Cobra Sexual Energy on NBI's own website includes the

following statement implying the product's purported acute effect:

> **SUGGESTED USE: Take one or two capsules in the afternoon and one or two capsules one hour prior to romantic activity.**[2]

(*See* Fitzgerald Dec. Ex. A at 7, 9.) NBI's website also includes more specific variations of the statements on Cobra Sexual Energy's packaging:

Cobra Sexual Energy Packaging	NBI Website
Yohimbine Bark Extract. Legendary herb from Africa that contains Yohimbine. Yohiminbine is intended to provide nutritive support for healthy blood flow	**Yohimbe –** Legendary herb from Africa that is believed to improve blood flow. Also contains Yohimbine.
Horny Goat Weed. From China, it is thought to support sensitivity in the sensory nerves.	**Horny Goat Weed –** Chinese herb, historically used to support sexual desire.
Muira Puama. Stimulating Brazilian herb known as "potency wood"	**Muira Puama –** Brazilian herb known as potency wood commonly used for supporting male performance.
Korean Ginseng. Most famous of all performance enhancing herbs. Ginseng is prized in the Orient.	**Korean Ginseng –** Also called Panax Ginseng, prized in the Orient for promoting energy and sexual endurance
Saw Palmetto. North American herb known for its reputed ability to help promote healthy prostate function.	**Saw Palmetto –** North American herb to support healthy prostate function
N/A	**Eleuthero –** Adaptogenic herb native to Siberia and China commonly used as nutritive support for adapting to stress and fatigue.

(*Id.*, Ex. A.) The information NBI provides to consumers via third-party channels goes even further, including statements such as:

- Yohimbine "improves blood flow to the sex organs" and "has been used in a popular prescription drug for impotence"

[2] This "Suggested Use" statement also appears on some bottles of Cobra Sexual Energy, though not on its exterior packaging. (*See* Fitzgerald Dec. Ex. D.)

> • "Horny Goat Weed – Chinese herb with testosterone-like effects"
>
> • "Saw Palmetto – North American herb proven to support healthy prostate function"
>
> • "Designed to enhance male reproductive health as well as sexual performance, Cobra from Natural Balance . . . improves male erectile function. Cobra contains Horny Goat Weed, which has been shown to improve sperm production, quality, and motility."

(*See id.* ¶¶ & Exs. E-F.)[3] Notably, the further the representation is seemingly removed from NBI, the more NBI is willing to make statements suggesting the product is drug-like, rather than a dietary supplement. Cobra Sexual Energy's packaging attempts to carefully skirt the line, while its website suggests acute use before "romantic activity," and third-party websites conveying information provided by NBI come outright and say the product is useful in treating impotence, erectile dysfunction, or prostate dysfunction. This paradigm is especially apparent when considering how NBI's statements about the saw palmetto in the product change depending on where they are made:

Cobra Sexual Energy Packaging	NBI's Cobra Sexual Energy Website	Third-Party Cobra Sexual Energy Website
Saw Palmetto. North American herb known for its reputed ability to help promote healthy prostate function.	**Saw Palmetto** – North American herb to support healthy prostate function	Saw Palmetto – North American herb proven to support healthy prostate function

[3] It is clear in context that the product information conveyed on third-party retailer sites is provided by NBI. Much of that information repeats verbatim information provided on Cobra Sexual Energy's packaging, or on NBI's website (such as the "Suggested Use" language). Third-party retailers would have no reason to modify or add language to what NBI provides. And, different third-party retailers show the same modified or added language, virtually assuring NBI is behind that consistent language. (*Compare* Fitzgerald Dec. Exs. E, G & H (using identical language including "has been used in a popular prescription drug for impotence," "testosterone-like effects," "proven to support healthy prostate function," etc.)

Thus, as the statement becomes decreasingly traceable to NBI, it turns from "herb known for its *reputed ability to help promote* healthy prostate function," to "herb to *support* healthy prostate function," to "herb ***proven to support*** healthy prostate function."

ARGUMENT

I. CAFA JURISDICTION IS PROPER

NBI's two oppositions represent its second attempt at arguing the Court lacks subject matter jurisdiction. Before the action was reassigned, the Honorable Marilyn L. Huff considered and rejected NBI's argument. *See Peviani v. Natural Balance, Inc.*, 2011 U.S. Dist. LEXIS 18110, at *3-5 (S.D. Cal. Feb. 24, 2011). NBI's latest effort demands no different result. Even assuming NBI's dubious retail sales estimate[4] of $3.2 million is correct, NBI ignores that under CAFA, the "jurisdictional minimum amount may be satisfied by considering claims for special and general damages, attorneys' fees, and punitive damages." *Brown v. Cornu*, 2009 U.S. Dist. LEXIS 56849, at *6 (N.D. Cal. July 1, 2009).

The Complaint prays for both attorneys' fees and punitive damages (Compl. at 24), and such awards are supported by Plaintiff's claims. *See, e.g., Gray v. Don Miller & Assocs., Inc*. 35 Cal. 3d 498, 505 (1984) (plaintiffs may recover fees under the UCL under "private attorney general" doctrine); Cal. Civ. Code § 1780(b), (d) (punitive damages available under the CLRA and prevailing CLRA plaintiff "shall" recover attorneys' fees and costs).

II. PLAINTIFF MEETS THE REQUIREMENTS OF RULE 23

A. Varying State Laws Do Not Defeat Commonality Because Plaintiff Seeks Certification of a Nationwide California Law Class; NBI Failed to Show Another State's Law Should Apply

NBI unnecessarily compares the laws of other states with California's, arguing that because they are so different, a class under each cannot be certified. (Cert. Opp. at 9-12). But Plaintiff seeks certification of a nationwide class under California law, not a class (or classes) that applies the consumer laws where each class member resides. Plaintiff's opening brief

[4] *See* Fitzgerald Dec. ¶¶ 13-17.

carefully described the choice-of-law rules that apply when a plaintiff seeks certification of a nationwide class under one state's law. (*See* Cert. Mot. 19-21.) *See generally Wolph v. Acer Am. Corp.*, 2011 U.S. Dist. LEXIS 35003, at *13-21 (N.D. Cal. Mar. 25, 2011) (after detailed choice of law analysis concluding conflict of law did not defeat typicality, and certifying class). NBI does not address any of Plaintiff's argument or authority, instead citing only irrelevant cases where courts concluded, unremarkably, that different state laws conflict.

B. Plaintiff's Gender Does Not Defeat Adequacy or Typicality as NBI Asserts

For the remainder of its Rule 23 argument, NBI conflates the standards for commonality, typicality and adequacy into a single argument based on Plaintiff's gender. In sum, NBI asserts, Plaintiff is not common/typical/adequate because (1) she is a female, whereas "typical" class members will be male consumers of the product, (2) she did not use the product whereas most class members will have used it, and (3) she supposedly did not rely on any statements about the product because she did not use it. (*See* Cert. Opp. at 12; *id.* at 12-14.) The first two arguments are wrong as a matter of law, the third as a matter of logic.

A recent California district court decision certifying a nationwide class under the UCL, FAL and CLRA reiterates the legal standard for each Rule 23 requirement laid out in Plaintiff's moving brief. *See Wolph*, 2011 U.S. Dist. LEXIS 35003. "Commonality requires that there be 'questions of fact and law which are common to the class.'" *Id.* at *11 (citing Fed. R. Civ. P. 23(a)(2)). This requirement "has been construed permissively" so that "[a]ll questions of fact and law need not be common . . . . The existence of shared legal issues with divergent factual predicates is sufficient, as is a common core of salient facts coupled with disparate legal remedies within the class." *Id.* at *12 (citing *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1019 (9th Cir. 1998) (commonality requirement satisfied because claims of proposed class stemmed from same source—defendant's product).

Like commonality, "the typicality requirement is applied permissively." *Id.* at *13.[5] "Representative claims are 'typical' if they are reasonably co-extensive with those of absent class members; they need not be substantially identical." *Id.* (citations and alterations omitted); *see also Heffelfinger v. Elec. Data Sys. Corp.*, No. CV 07-101, 2008 U.S. Dist. LEXIS 5296, at *59 (C.D. Cal. Jan. 7, 2008) (quoting *Hanlon*, 150 F.3d at 1020, and citing *Schwartz v. Harp*, 108 F.R.D. 279, 282 (C.D. Cal. 1985) ("A plaintiff's claim meets this requirement if it arises from the same event or course of conduct that gives rise to claims of other class members and the claims are based on the same legal theory.")).

Moreover, "[i]n determining whether typicality is met, the focus should be 'on the defendants' conduct and plaintiff's legal theory,' not the injury caused to the plaintiff." *Id.* at *13-14 (quoting *Simpson v. Fireman's Fund Ins. Co.*, 231 F.R.D. 391, 396 (N.D. Cal. 2005) (in turn quoting *Rosario v. Livaditis*, 963 F.2d 1013, 1018 (7th Cir. 1992)). "[T]ypicality is 'satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability." *Id.* at *14 (quoting *Armstrong v. Davis*, 275 F.3d 849, 868 (9th Cir. 2001) (citation omitted)).[6] *See also Dukes v. Wal-Mart*, 509 F.3d 1168 (9th Cir. 2007) ("Some degree of individuality is to be expected in all cases, but that specificity does not necessarily defeat typicality.")

In sum, typicality exists unless "the named plaintiff's individual circumstances are *markedly different* or . . . the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based." *Tanne v. Autobytel, Inc.*, 226

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[5] In practice, "the commonality and typicality requirements of Rule 23(a) tend to merge . . . ." *Heffelfinger v. Elec. Data Sys. Corp.*, 2008 U.S. Dist. LEXIS 5296, at *60 (C.D. Cal. Jan. 7, 2008).

[6] NBI argues in a section titled "Adequate Representation," that Plaintiff is inadequate because her claims of reliance are supposedly implausible. The adequacy requirement has to do with whether the "representative . . . will fairly and adequately protect the interests of the class," Fed. R. Civ. P. 23(a)(4), including whether the proposed representative has any conflicts of interest. NBI's argument, notwithstanding its labeling, therefore appears to be one relating to commonality or typicality, and we treat it as such. *See generally Wolph*, 2011 U.S. Dist. LEXIS 35003, at *22-24.

F.R.D. 659, 667 (C.D. Cal. 2005) (emphasis added) (citing *Takeda v. Turbodyne Techs., Inc.*, 67 F. Supp. 2d 1129, 1136-37 (C.D. Cal. 1999)).

Here, Plaintiff's claims are not "markedly different," but rather typical because, like other class members, she purchased Cobra Sexual Energy during the class period after exposure to materially false and misleading labeling claims. *See Estrella v. Freedom Fin. Network, LLC*, 2010 U.S. Dist. LEXIS 61236, at *32-33 (N.D. Cal. June 2, 2010) (Finding typicality requirement met and certifying false and misleading advertising class because "[P]laintiffs have sufficiently alleged that the misrepresentations they have identified were material."); *Cartwright v. Viking Indus.*, 2009 U.S. Dist. LEXIS 83286, at *18 (E.D. Cal. Sept. 11, 2009) ("[B]ecause the purported class member's claims all arise from the same or similar course of conduct and resulted in the same or similar injury, the typicality requirement is satisfied."); *Collins v. GameStop Corp.*, 2010 U.S. Dist. LEXIS 88878, at *8-9 (N.D. Cal. Aug. 6, 2010) (class action allegations plausible where individualized reliance may be presumed if alleged misrepresentation is material); *see also Tobacco II*, 46 Cal. 4th at 327 (misrepresentation is "material" if a reasonable person "would attach importance to its existence or nonexistence in determining his choice of action" (citation omitted)); *Morgan v. AT&T Wireless Servs., Inc.*, 177 Cal. App. 4th 1235 (2009) (same); *McAdams v. Monier, Inc.*, 182 Cal. App. 4th 174, 186-91 (2010) (plaintiff stated CLRA and UCL claims typical of the class's claims based on the same alleged material misrepresentation made to each class member); *Steroid Hormone*, 181 Cal. App. 4th at 156-57 (plaintiff entitled to show alleged misrepresentation was material).

NBI nevertheless asserts Plaintiff fails to meet the commonality and typicality requirements because she is subject to a "unique defense"—that she is a woman who did not herself consume the product she purchased for her husband. (*See* Cert. Opp. at 11-14). This is a rehash of an argument rejected by Judge Huff less than two months ago, who held:

> The Court also concludes that Plaintiff has properly alleged reliance and injury in fact. In her complaint, Plaintiff alleges that she suffered an economic injury because she paid more for the product than she would have absent the deceptive statements on its labels. (Compl. ¶ 79.) This economic injury for lost money is "a classic form of injury in fact." Plaintiff further alleges that she suffered this injury

> in fact when she purchased the product after reading and relying on the false and misleading statements contained on the product's label. (Compl. ¶¶ 8, 76-83.) These allegations are sufficient to properly plead reliance. Further, despite Natural Balance's assertions, there is no requirement that the purchaser of the product use the product herself to have relied on the statements and suffered an injury. Accordingly, the Court concludes that Plaintiff has established that she has standing to bring her UCL and FAL claims.

Peviani, 2011 U.S. Dist. LEXIS 18110 at *8-9 (S.D. Cal. Feb. 24, 2011) (internal citations omitted) (citing *Kwikset v. Sup. Ct.*, 51 Cal. 4th 310, 323 (2011); *Laster v. T-Mobile USA, Inc.*, 407 F. Supp. 2d 1181, 1194 (S.D. Cal. 2005); *Williams v. Gerber Prods. Co.*, 523 F.3d 934, 939 n.3 (9th Cir. 2008) (finding that plaintiff sufficiently pled claims under the UCL and CLRA based on the purchase of fruit juice snacks for her children's consumption rather than her own)).

Nevertheless, NBI argues Plaintiff is not adequate because her "claim of reliance . . . is simply not plausible here." (Cert. Opp. at 13.) Setting aside that it is perfectly plausible a woman would rely on a product's label claims when purchasing it for her husband,[7] just as a mother plausibly relies on juice labels in purchasing the product for her children, *Williams*, 523 F.3d 934, the heightened reliance NBI demands is not an element of Plaintiff's claims.

An individual need not prove she relied on a deceptive claim under the UCL, but only that it is objectively deceptive to a reasonable consumer. Thus "relief under the UCL is available without individualized proof of deception, reliance and injury." *Chavez v. Blue Sky Natural Bev. Co.*, 268 F.R.D. 365, 376 (N.D. Cal. 2010) (certifying nationwide UCL class alleging defendant misleadingly labeled soft drinks). This is because "the UCL's focus [is] on the defendant's conduct, rather than the plaintiff's damages, in service of the statute's larger purpose of protecting the general public against unscrupulous business practices." *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009).

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[7] Just as NBI asserted in its Motion to Dismiss, it again claims "***Nowhere in plaintiff's complaint*** does she allege she purchased the product for someone else. In fact, plaintiff states she purchased it for 'her own' use." (Cert. Opp. at 13 (emphasis in original)). This is false. The Complaint alleges plaintiff "purchased Cobra for her own and household use." (Compl. ¶ 9.) To the extent "household use" was vague—even in light of Judge Huff's decision denying dismissal on this basis—Plaintiff's Motion for Preliminary Injunction stated she "purchased the product for her husband's use, and both their enjoyment." (PI Mot. at 2.)

See also Annunziato v. eMachines, Inc., 402 F. Supp. 2d 1133, 1137-38 (C.D. Cal. 2005) (

> The goal of both the UCL and the FAL is the protection of consumers. However, the Court can envision numerous situations in which the addition of a reliance requirement would foreclose the opportunity of many consumers to sue under the UCL and the FAL. . . . A construction of these statutes that reduced them to common law fraud would not only be redundant, but would eviscerate any purpose that the UCL and the FAL have independent of common law fraud.)

Alternatively, NBI argues Plaintiff is inadequate because "[w]hile plaintiff may have purchased the product, she has little else in common with other proposed class members. She has never used the product. It is a 'men's formula' and therefore men who have used the product would be class members, not women who have never used the product." (Cert. Opp. at 14.)

While the question of whether someone consumed a product might be relevant if Plaintiff made personal injury claims, the claim here is economic fraud. This fraud occurred the moment Plaintiff purchased the product in reliance on its representations, even though she bought it for her husband's use and never intended to use it herself. What Plaintiff or any other class member did with the product after purchasing it is irrelevant.[8] *See, e.g.*, *Chacanaca v. Quaker Oats Co.*, 2010 U.S. Dist. LEXIS 111981, at *34-35 (N.D. Cal. Oct. 14, 2010) ("The injury alleged here is the *purchase* of food products . . . the plaintiffs find objectionable. . . .[P]laintiffs have adequately alleged an injury directly related to the redress they seek."). *Accord Wolph,* 2011 U.S. Dist. LEXIS 35003, at *21-22 (

> Though Acer cites evidence that the Wolphs' particular use of their notebook computer or other factors caused the alleged problems, the typicality of the claims at issue here arises from the question whether Acer sold notebook computers that were incapable of properly operating the . . . system with which they were marketed, packaged and sold. That conduct by Acer is not unique to the named Plaintiffs here.)

Rather, as Plaintiff argued in her opening brief, there are several common questions of law and fact (Cert. Mot. at 6). Moreover, the common proof in this case is NBI's labeling of

[8] The absurdity of Defendant's argument that consumption of a product is required in order to assert a consumer fraud claim is clear when one considers it would mean a class action against the maker of pet food could not be maintained unless the pet-owner class representative swallowed some down.

Cobra Sexual Energy. The claims of Plaintiff and the class "stem from the same set of core facts as to whether [NBI] sold [Cobra Sexual Energy]" in an unlawful and deceptive manner during the class period. *Wolph*, 2011 U.S. Dist. LEXIS 35003, at *12-13.

C. Causation and Reliance are not Predominating Individual Issues

In her opening brief, Plaintiff identified several issues common to each class member's claims (Cert Mot. at 6), and showed that reliance is not an element of her claims (*id.* at 14-15). NBI nevertheless argues that causation and reliance are "individual issues" demanding the denial of class certification. NBI is wrong.

NBI cites *Vioxx* for the proposition that each class member must show harm as a result of the conduct, but that court recognized that in order to obtain a remedy for deceptive advertising, "a UCL plaintiff need only establish that members of the public were likely to be deceived by the advertising, . . . it is clear from Supreme Court authority that recovery in a UCL action is available in the absence of individual proof of deception, reliance, and injury." *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 130 and 134 n. 19 (2009). Moreover, there is no real analogy between *Vioxx* and this action given certification was denied in *Vioxx* because two key aspects of the plaintiffs' case required individual inquiry. The court found, based upon extensive medical and other evidence, that the determination of whether Vioxx was no more effective and less safe than the generic medication "depende[d] on each individual patient's specific medical needs and history." 180 Cal. App. 4th at 126. Plaintiff's claim that the manufacturer misrepresented the effectiveness and safety of Vioxx could not be proved on a class-wide basis because, for many patients, despite its drawbacks, there was no more safe or effective product. NBI makes no similar "extensive medical" showing that its claims about how Cobra Sexual Energy treats impotence, erectile dysfunction, or prostate dysfunction may, for some purchasers, be true.

NBI also misapplies the holding in *Sevidal*. (Cert. Opp. at 17.) That case involved a computer error that sometimes caused the statement "Made in the USA" to appear on a retailer's website describing an imported product. Defendant showed, however, that the "Made in the USA" claim was only displayed on the computer screen of, at most, seventeen percent of buyers,

thus "a majority of the class members were never exposed to the alleged misrepresentation." *Sevidal v. Target Corp.*, 189 Cal. App. 4th 905, 926 (2010). The court never held class members had to "see" the misrepresentation, but only be "exposed" to it, and contrasted the situation before it with cases like this one, where "each consumer of the product was exposed to the misrepresentation." *Id.* (discussing *Weinstat v. Dentsply Int'l, Inc.*, 180 Cal. App. 4th 1213 (2010) (district court abused discretion in decertifying class based on alleged misrepresentation that occurred in product manual that came with dentist water-spraying device)). By contrast, the statements alleged to be misleading here appear on the label of Cobra Sexual Energy. Thus, every purchaser class member was exposed to the deceptive claims.

D. Certification Under Rule 23(b)(2) is Appropriate Because the Predominating Goal of this Suit is Permanently Enjoining Defendant's Dangerous and Fraudulent Conduct, and Obtaining the Equitable Remedy of Restitution

In her motion for class certification Plaintiff demonstrated that under applicable Ninth Circuit standards, her claims for the equitable relief of restitution and injunction predominate over her claim for money damages. (Cert. Mot. at 8-11.) NBI nevertheless argues monetary relief predominates, and Rule 23(b)(2) certification is therefore inappropriate, because (1) Plaintiff has supposedly not yet adduced evidence of the dangers of Cobra Sexual Energy, and (2) the only damage Plaintiff claims is the purchase price of the product. (Cert. Opp. at 15.)

First, Plaintiff cited substantial evidence of the dangers of both the yohimbine and saw palmetto in Cobra Sexual Energy in her concurrently-filed Motion for Preliminary Injunction. (PI Mot. at 4-7.) But Plaintiff's claims are not limited to the danger presented by Cobra Sexual Energy (rather, it is that danger which justifies preliminary injunctive relief). Instead, Plaintiff alleges many of the herbs in Cobra Sexual Energy are *ineffective*.

Second, the merits inquiry NBI requests is, in any event, inappropriate for resolution on a motion for class certification. Plaintiff does not need to show that she will prevail on her equitable claims, only that they predominate over her monetary claims. "[T]he predominance test turns on the primary goal and nature of the litigation—not the theoretical or possible size of the total damages award." *Dukes v. Wal-Mart Stores, Inc.*, 603 F.3d 571, 618 (9th Cir. 2010). Thus,

"[a] comparison between the amount of monetary damages available *for each plaintiff* and the importance of injunctive and declaratory relief for each is far more relevant to establishing predominance than the total size of a potential monetary reward." *Id* (emphasis in original). Here, Plaintiff seeks the equitable remedy of restitution, an injunction barring NBI's continuing dangerous and deceptive conduct, and an order for a corrective advertising campaign alerting consumers that Cobra Sexual Energy is ineffective. Such relief is of far greater value to consumers and the general public than nominal refunds on their Cobra Sexual Energy purchases.

III. PLAINTIFF IS LIKELY TO SUCCEED ON THE MERITS

NBI asserts that Plaintiff's claims are "not viable" (Cert. Opp. at 17-25) or "lack merit" (PI Opp. at 7), because Cobra Sexual Energy's label is supposedly permitted by federal regulations for dietary supplements promulgated pursuant to the Dietary Supplement Health and Education Act of 1994. As a threshold matter, Plaintiff's claims having survived NBI's Rule 12(b)(6) motion, it is inappropriate to further consider the merits on her Motion for Class Certification—instead, that inquiry must focus only on the requirements of Rule 23. *See, e.g.*, *Bautista-Perez v. Holder*, 2009 U.S. Dist. LEXIS 63446, at *20-21 (N.D. Cal. July 9, 2009) (Plaintiffs "claims do not lack commonality simply because a legal question . . . remains for resolution at the merits stage of litigation.").

But even considering the substance of NBI's claim in the context of Plaintiff's motion for preliminary injunction (in which Plaintiff must show a likelihood of success on the merits), NBI is wrong for three reasons. First, FDA regulations define Cobra Sexual Energy as an over-the-counter aphrodisiac drug product, 21 C.F.R. § 310.528(a), which subjects the product to regulations NBI violates, *see id.* at § 310.528(b). In arguing Cobra Sexual Energy is not subject to the requirements of § 310.528(b) because that section "prohibits OTC drugs—not dietary supplements—from using aphrodisiac claims" (Opp. at 15-16), NBI ignores that Cobra Sexual Energy is captured within the definition of an OTC aphrodisiac drug product, set forth in §

310.528(a).[9] Second, even if an article like Cobra Sexual Energy purports to be a dietary supplement, it is a drug and is regulated as a drug if its label suggests it is "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(B)-(C). Cobra Sexual Energy includes a number of labeling claims the FDA has declared imply the product is intended to be used in the treatment of impotence or erectile dysfunction, and which therefore renders the product a drug under these sections. Third, Cobra Sexual Energy does not meet several of the requirements for permitted structure/function dietary supplement claims, further suggesting it should be regulated as a drug, rather than a dietary supplement.

But even if Cobra Sexual Energy were a dietary supplement as NBI urges, Plaintiff is still likely to succeed on her claims because Cobra Sexual Energy's labeling violates those regulations too. And, regardless of its classification, Cobra Sexual Energy makes impermissible health claims further supporting liability.

A. The Statutory Framework

The DSHEA amended the FDCA to encompass dietary supplement-specific provisions, including the definition of "dietary supplement," product safety, nutritional statements and claims, ingredient and nutritional labeling, good manufacturing procedures, and the classification of new dietary ingredients. Under the DSHEA, a dietary supplement is (1) a product (other than tobacco) intended to supplement the diet, which contains at least one vitamin, mineral, herb or other botanical, amino acid, a substance to increase total daily caloric intake, or a concentrate,

[9] Like much of its argument about the regulations applicable to Cobra Sexual Energy, NBI relies on Hyman, Phelps & McNamara's Letter Brief, submitted as Exhibit H to the Monroy Declaration (*see* Dkt. Nos. 26-2, 27-2 (Declaration) & 26-10, 27-10 (Letter Brief)). The Letter Brief constitutes legal argument submitted to the Court in opposition to a motion, but is signed by an attorney not admitted to practice in California or before this Court and who has not made an appearance in this case. NBI's submission of the Hyman Letter Brief appears to violate Fed. R. Civ. P. 11(a), requiring a party's attorney of record to sign all briefs submitted to the Court, and Civ. L. R. 83.3(c)(2), which provides "only members of the bar of this court shall practice in this court." Moreover the combination of the single-spaced, 7-page Letter Brief and NBI's opposition briefs violates the Court's page limit for oppositions. Plaintiff respectfully requests the Hyman Letter Brief be stricken.

metabolite, constituent, or extract; (2) is ingested in pill, capsule, tablet or liquid form; (3) is not represented for use as a conventional food or the sole item of a meal or diet; and (4) is labeled as a "dietary supplement." *See* 21 U.S.C. § 321(ff). While the DSHEA permits certain claims, it prohibits claims that expressly or by implication suggest a product can prevent, treat or cure specific diseases or disorders.

The DSHEA also established the Commission on Dietary Supplement Labels, which was commissioned to study dietary supplement labeling and provide recommendations for the promulgation of regulations to implement the DSHEA. The Commission's final report provides important insight into the purposes behind and requirements of the DSHEA.

According to the Commission, what NBI refers to as permissible "structure/function" claims (*see* PI Opp. at 9) are in fact statements of nutritional support. Such statements may be made in the labeling of dietary supplements provided they (1) claim a benefit related to a classical nutrient deficiency disease; (2) describe the role of a nutrient or dietary ingredient intended to affect structure or function in humans; (3) characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain structure or function; or (4) describe general well-being from consumption of a nutrient or dietary ingredient.[10]

Such statements "are nearest in usage to the types of statements that might otherwise be considered to be health claims or drug claims." *Id.* at 36. The hallmark of a permissible structure/function statement of nutritional support, then, is that the statement links nutrients with growth, health, and well-being, generally, without reference—direct or implied—to a specific disease or dysfunction. Thus, in the context of food labeling, the statement that "calcium builds strong bones and teeth" is a classic example of an allowable structure/function statement of nutritional support. *See id.*

Such permissible structure/function statements of nutritional support may appear on the

[10] *See* Commission on Dietary Supplement Labels, *1997 Report of the Commission on Dietary Supplement Labels*, at 35 (hereinafter "Final Report"), *available at* http://www.nutriwatch.org/09Reg/dslabels.pdf.

label of a dietary supplement provided certain requirements are met. DSHEA requires manufacturers notify the FDA within 30 days after first marketing a product with a statement of nutritional support, that the manufacturer have substantiation for the statement, and that the label include a disclaimer providing "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." *See id.*; *see also* 21 U.S.C. § 343(r)(6) (laying out requirements).

The Commission's Report notes several important points. First, "claims for dietary supplements that meet the definition of health claims, as defined under the NLEA, should continue to be regulated under the same NLEA provisions that apply to conventional foods." *Id.* Second, when evaluating potential structure/function nutritional support claims, "[s]ome Commission members believed . . . statements [referring to organs] were either drug claims or NLEA health claims," especially in light of the fact that the "FDA has defined a disease or health-related condition to include damage to an organ, part or structure of the body . . . ." *Id.* at 37. Third, "[s]tatements of nutritional support relating to structure or function should not be used to imply effects that are currently considered prescription drug claims." *Id.* Finally, "[s]tatements of nutritional support that ***mention acute effect on the structure or function*** of a major system . . . raise particular concern for some Commission members. In contrast, effects on stress, mental acuity, or bone or skin health within the normal range seemed to carry less serious connotations." *Id.* (emphasis added). As a result of these observations, the Commission issued a series of Findings outlining how the DSHEA should be interpreted and implemented. These include:

- Statements of nutritional support should be supported by scientifically valid evidence[11] substantiating that the statements are truthful and not misleading;

- Statements of nutritional support should only be made where they do not suggest

[11] Elsewhere, the Commission describes the applicable standard of evidence for manufacturer substantiation in the following way: "significant scientific agreement among experts qualified by scientific training and experience to consider whether a claim is supportable. . . . Significant scientific agreement is to be based on the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles." *See id.* at 30.

disease prevention or treatment;

• Statements that mention a body system, organ or function affected by the supplement using terms like "maintain," "support," or "promote" are only appropriate where they do not suggest disease prevention or treatment; and

• Statements of nutritional support should be distinct from NLEA health claims, defined as claims that characterize the relationship between a nutrient or a food component and a specific disease or health-related condition, and should not state or imply a link between the supplement and prevention of a specific disease or health-related condition.

B. General Principles Concerning the Classification of an Article as Drug or Dietary Supplement

Under 21 U.S.C. § 321(g)(1), products that are intended to affect the structure or function of the body, or for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, are drugs. As NBI acknowledges, "the regulatory classification of a product under the [FDCA] is determined by its intended use, as evidenced primarily by its labeling." (PI Opp. at 9.) The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution. 21 C.F.R. § 201.128. Such intent may even be shown where the article is, with the knowledge of its producer, being offered and used for a purpose for which it is neither labeled nor advertised. *Id.* The FDA regularly looks to a product's web advertising when determining whether a product is a drug. In sum, the determination of whether a product is a drug is a context-specific, case-by-case analysis taking into account the totality of the circumstances.

By contrast, permissible dietary supplement structure/function statements of nutritional support claim a benefit related to a classical nutrient deficiency disease, describe the role of a nutrient or dietary ingredient intended to affect structure or function in humans, characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain structure or function, or describe general well-being from consumption of a nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6).

In order for Cobra Sexual Energy to be considered a mere dietary supplement, the Court must be convinced that, given the totality of the circumstances, NBI does not suggest Cobra

Sexual Energy may be useful in treating impotence, erectile dysfunction, or prostate dysfunction.

C. Cobra Sexual Energy is an "Aphrodisiac Drug Product"

NBI asserts Cobra Sexual Energy is not subject to the requirements of 21 C.F.R. § 310.528(b) because the product is a dietary supplement rather than an "OTC drug product." This puts the cart before the horse and ignores the plain language of § 310.528(a), in which the FDA declares what exactly constitutes an "aphrodisiac drug product" subject to the requirements of § 310.528(b).

Section 310.528 is titled, "Drug products containing active ingredients offered over-the-counter (OTC) for use as an aphrodisiac." Plaintiff demonstrated in her opening brief in support of Preliminary Injunction that Cobra Sexual Energy unquestionably meets the definition of an aphrodisiac drug product under this section, (PI Mot. at 1:8-2:9), subjecting the product to various requirements of § 310.528(b), which NBI violates. Without refuting that analysis, NBI claims in conclusory fashion that the regulation applies to "OTC drugs – not dietary supplements" (PI Opp. at 15, Dkt. No. 27.) This argument draws a false distinction.

The term, "OTC drug product" is not separately defined in the FDCA, but rather refers only to the term as set forth and defined within § 310.528. That section alternatively refers to products that bear labeling claims relating to sexual arousal, desire or performance, as "an aphrodisiac drug product," "aphrodisiacs for OTC use," "aphrodisiac drug products for OTC use" and an "OTC drug product." NBI further claims—via the Hyman, Phelps & McNamara Letter Brief, rather than in its Opposition—that because § 310.528 "preceded the enactment of the DSHEA," and because the FDA has supposedly approved some aphrodisiac claims for other dietary supplements, "[t]o interpret [§ 310.528] as precluding aphrodisiac claims in the labeling of dietary supplements would render meaningless both section 403(r)(6) . . . and [the] FDA's subsequent statements confirming that aphrodisiac claims are permitted for dietary supplements." (Hyman Letter Br. at 6, Dkt. Nos. 26-10, 27-10.) This argument turns congressional intent on its head.

If § 310.528 existed in the same form both before and after Congress passed the DSHEA,

then Congress must have intended it to survive new regulations for dietary supplements. The section need not be read in conflict with 21 U.S.C. § 343(r)(6), as NBI suggests, (*id.*). By its plain language, if a non-prescription product that would otherwise qualify as a dietary supplement under § 343(r)(6) contains the ingredients noted in § 310.528(a) and makes claims of the type described in § 310.528(a), the product is an aphrodisiac drug product subject to § 310.528(b), which NBI violates. (*see* PI Mot. at 11, Dkt. No. 11).

Less than a year ago, the FDA issued a Warning Letter concerning a product called Libido Edge Capsules Natural Sexual Enhancement, which claimed that the Bulgarian Tribulus Terrestris and Muria Puama Extract in the product could help with impotence. (*See* Plaintiff's Request for Judicial Notice ("RJN") Ex. A.) The FDA determined these claims rendered the product an OTC drug product, subjecting it to the regulations under 21 C.F.R. § 310.528. (*Id.* at 2.) As a result, the FDA concluded, Libido Edge Capsules Natural Sexual Enhancement violates 21 U.S.C. § 355(a) (requiring such drugs to have an approved application under 21 U.S.C. § 355(b) before they can be marketed); § 352(f)(1) (product misbranded where adequacy for indications for labeled uses have not been established); and § 352(o) (misbranded unless manufactured, prepared, propagated, compounded or processed in registered establishment). (*Id.*)

D. Cobra Sexual Energy is a Drug Because Its Label Suggests it is Intended for Use in the Diagnosis, Cure, Mitigation, Treatment, or Prevention of Impotence, Erectile Dysfunction, or Prostate Dysfunction

Cobra Sexual Energy's labeling includes the following "therapeutic" claims that render it a drug within the meaning of 21 U.S.C. § 321(g)(1)(B), because they suggest the product may be useful in treating a specific condition:

Third-Party Website Claims

- "Take one or two capsules in the afternoon and one or two capsules one hour prior to romantic activity";
- Yohimbine "improves blood flow to the sex organs" and "has been used in a popular prescription drug for impotence";
- "Horny Goat Weed – Chinese herb with testosterone-like effects";

• "Saw Palmetto – North American herb proven to support healthy prostate function"; and

• "Designed to enhance male reproductive health as well as sexual performance, Cobra from Natural Balance . . . improves male erectile function. Cobra contains Horny Goat Weed, which has been shown to improve sperm production, quality, and motility."

NBI Website Claims

• "Take one or two capsules in the afternoon and one or two capsules one hour prior to romantic activity."

Cobra Sexual Energy Packaging/Label

• "Take one or two capsules in the afternoon and one or two capsules one hour prior to romantic activity." (Appears on some bottles of Cobra Sexual Energy, *see* Fitzgerald Dec. Ex. D);

• Saw palmetto "promote[s] healthy prostate function";

• Horny Goat Weed "support[s] sensitivity in the sensory nerves"; and

• Yohimbe "provide[s] nutritive support for healthy blood flow" and "improve[s] blood flow."

That the FDA considers such claims evidence an article is a drug is reflected in several of its recent warning letters. *See* RJN Ex. B (FDA Warning Letter to Alternative Health & Herbs Remedies, dated January 16, 2007) (labeling of product "Use for . . . prostate problems," caused product to be drug within meaning of 21 U.S.C. § 321(g)(1)(B)); Ex. C (FDA Warning Letter to Banyan Trading Co., dated June 29, 2009 (labeling of product "Traditional uses: . . . impotence, . . . enlarged prostate" caused product to be drug within meaning of 21 U.S.C.§ 321(g)(1)(B)); Ex. D (FDA Warning Letter to American Nutraceuticals Co., dated November 6, 2003 (claims including "helpful in treating impotence" and "formulated to help with disorders of the prostate" rendered article drug within meaning of § 321(g)(1)(B)).

E. Cobra Sexual Energy is a Drug Because Its Label Suggests it Affects the Structure and Function of the Body

Cobra Sexual Energy's labeling includes several claims that render it a drug within the meaning of 21 U.S.C. § 321(g)(1)(C) because they suggest the product is intended to affect the

structure or function of the body. This is particularly true with the product's "Suggested Use," which implies an acute effect ("take one or two capsules one hour before romantic activity"), something the FDA has consistently held renders a product a drug. Other statements that suggest or imply the product is intended to affect the structure or any function of the body include:

- "Sexual Energy" (product name);
- "Powerful Men's Formula"
- "enhance [] sexuality and improve [] performance"
- "Take Virility to the Max!"
- "sensitivity in the sensory nerves"
- "potency wood"
- "performance enhancing herbs"

The FDA has held such statements render an article a drug. In a recent Warning Letter, the FDA found the following claims, when made on products that, like Cobra Sexual Energy, were labeled as dietary supplements, nevertheless rendered the products drugs within the meaning of 21 U.S.C. § 321(g):

- "INCREASED SEX DRIVE, STAMINA AND VIRILITY FOR MEN"
- "MALE SEXUAL VITALITY ENHANCER"
- "As a dietary supplement, take 1-2 capsules 45 minutes before sexual activity"
- "SEXUAL BOOSTER"
- "INCREASES STAMINA"
- "take one capsules 30-45 minutes before sexual activity"
- "All-Natural Male Performance Pill"
- "Take 1-2 capsules 1-2 hours before sexual activity."

See RJN Ex. E (Letter from FDA to NovaCare, LLC, dated December 28, 2010). As the FDA concluded, statements like these "make clear that the . . . products are drugs under section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(C)] because they are intended to affect the structure or function of the human body." *See also* RJN Ex. F (Letter from FDA to Kanec USA, Inc., dated October 8, 2010) (

> Statements on your products labels describe their intended uses. Specifically, the labels of 'STUD Capsule For Men' and 'XOX For Men' state, '[W]orks in as

> quickly as 45 minutes and helps increase sexual pleasure and improve sexual performance.' This statement makes clear that 'STUD Capsule For Men' and 'XOX For Men' are intended to affect the structure or function of the human body and/or prevent, treat, or cure disease conditions. Accordingly, 'STUD Capsule For Men' and 'XOX For Men' are drugs, as defined by Section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1).);

RJN Ex. C (Letter from FDA to Natural Wellness, LLC, dated October 5, 2010) (statements on product and website like "ENHANCE YOUR PERFORMANCE," "enhance frequency and duration of sensual arousal," and "increases arousal . . . enhances the sensations" rendered a purported dietary supplement a drug within the meaning of 21 U.S.C. § 321(g)(1)).

Finally, many of the Warning Letters also make clear that a product is not a dietary supplement if it contains a substance approved as a drug, since 21 U.S.C. § 321(ff) limits dietary supplement substances to an enumerated list of dietary ingredients, which does not include pharmaceutical agents. (*See, e.g.*, RJN Exs. E, F.) NBI's assertion that Yohimbine "has been used in a popular prescription drug for impotence," if true, renders Cobra Sexual Energy a prohibited new drug.

F. Cobra Sexual Energy is a Drug Because If Cobra Sexual Energy Were a Dietary Supplement, it Would Be Misbranded

Structure/function statements on dietary supplements are permitted only where they meet five criteria: (1) The statement must claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States, describe the role of a nutrient or ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which the nutrient or ingredient acts to maintain such structure or function, or describe the general well-being from consumption of a nutrient or ingredient; (2) the manufacturer must have substantiation that the statement is truthful and not misleading; (3) the statement must contain, prominently displayed in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."; (4) the statement may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases; and (5) the manufacturer

has notified the Secretary no later than 30 days after first marketing the dietary supplement with the statement, that the statement is being made. 21 U.S.C. § 343(r)(6). NBI fails all five criteria.

First, NBI has not shown how any of the challenged statements meet the vague standards of the first criteria, as opposed to specific suggestions of the treatment of impotence.

Second, as laid out in detail in Plaintiff's Complaint, NBI has no substantiation that many of its claims are truthful and not misleading. Claims that lack substantiation cause a product to be misbranded under FDCA §§ 403(a)(1) and 403(r)(6). NBI's only response is to copy the abstract of a **1987** British study about the apparent efficacy of yohimbine, which is just one of the many ingredients in Cobra Sexual Energy (PI Opp. at 17-18). This falls well short of NBI's obligation under the FDCA. Moreover, the Act provides that aphrodisiac claims like those NBI makes with respect to Cobra Sexual Energy are "unsupported by scientific data." 21 C.F.R. § 310.528. In sum, even if Cobra Sexual Energy is a dietary supplement, because its claims cannot be substantiated, they may not be made and NBI is in violation of the Act.

Third, the packaging of Cobra Sexual Energy, and the bottle itself—at least in some or most versions sold during the class period—did not include the required disclaimer, "This statement has not been evaluated by the FDA . . . ." (*See* Compl. at 7-13; Fitzgerald Dec. Ex. D.) This factor is particularly strong in suggesting Cobra Sexual Energy is a drug. *See Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056, 1065-66 (2002):

> [21 U.S.C. § 343(r)(6)] allows a statement to be made on the label of a dietary supplement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." If such a statement is made, then part (r)(6)(C) requires this disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." * * * The obvious reason for this federally required disclaimer is to tell the consumer that the product is not a drug.

Fourth, as discussed above, Cobra Sexual Energy's labeling contains statements that suggest its use in treating impotence, erectile dysfunction, or prostate dysfunction.

Fifth, NBI did not, as it was required, notify the Secretary that it was using the challenged statements, which is evident from NBI citing other notification letters, but omitting any

allegation that it complied with the rule itself.[12]

G. Cobra Sexual Energy Makes Impermissible Health Claims

Regardless of its classification, Cobra Sexual Energy makes the impermissible health claim, "supports prostate function." The FDCA defines health claims as statements that characterize a relationship between a nutrient or food component and a specific disease or health-related condition. *See* 21 C.F.R. § 101.14(a)(1). A "disease or health-related condition" means "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension) . . . ." 21 C.F.R. § 101.14 (a)(5). Because the claim, "supports prostate function," relates to damage to an organ (the prostate) such that it is not functioning properly, and relates to the general state of prostate illness leading to such dysfunctioning (for example, symptoms consistent with PBH, enlarged prostate, etc.), NBI's claim that Cobra Sexual Energy "supports prostate function" (and claims that go further, such as "proven to support prostate function") is an impermissible health claim.

[12] The Court should not read much into the fact that NBI was able to locate a few notification letters for similar statements to those challenged in the lawsuit, to which the FDA did not apparently object. (PI Opp. at 15.) The FDA is inundated with such notification letters, and simply does not have the resources to review and object to every notification, thus the absence of objection is not evidence of assent. The Commission on Dietary Supplement Labels acknowledged this, recommending that, "***To the extent resources permit***, FDA should continue to provide guidance to manufacturers by responding to letters of notification when the agency deems a proposed statement to be inappropriate . . . ." (Final Report, *supra* n. 10, at 39 (emphasis added)). The FDA's failure to object to a single notification letter does not render the plain language of the FDCA and its regulations inapplicable. Moreover, NBI's citation of FDA comments in the federal register (PI Opp. at 14) *supports* Plaintiff's position. According to the FDA, claims that use the word "potency"—like Cobra Sexual Energy's claim, "potency wood"—imply treatment of impotence, a disease. And, the FDA said, other aphrodisiac claims on Cobra Sexual Energy "could be" permissible only if "these claims made clear that they were intended *solely for decreased sexual function associated with aging*." (65 Fed. Reg. at 1031). Nowhere does Cobra Sexual Energy mention or imply the product is solely for decreased sexual function associated with aging—in fact, it associates decreased sexual function with prostate dysfunction and impotence—diseases.

IV. INJUNCTIVE RELIEF IS WARRANTED

NBI's remaining arguments are without merit. First, NBI's citation to a single summary sentence without any underlying authority for the proposition that saw palmetto "does not appear to affect readings of . . . PSA[] levels" (PI Opp. at 16) is insufficient to rebut the weight of the evidence presented by Plaintiffs on this point, including citations to scientifically sound, peer-reviewed studies (PI Mot. at 5-7).[13] Further, NBI is wrong that its confusing purported warning, beginning "Contraindicated for," substitutes for the crucial advice of and monitoring by a physician when using MAO inhibitors. Finally, NBI complains of burden in supposedly having to recall its product if the Court issues an injunction. Setting aside that NBI should be required to shoulder any burden caused by unlawfully marketing its product, Plaintiff seeks injunctive relief limited to "enjoining [NBI] from manufacturing, distributing, or marketing [Cobra Sexual Energy] using the false and misleading tactics that are the subject of this suit." (PI Not. of Mot.) While this would prevent NBI from further distributing Cobra Sexual Energy with its current packaging, Plaintiff does not seek the recall from store shelves NBI describes as burdensome.

CONCLUSION

Plaintiff respectfully requests the Court grant her Motions for Class Certification and Preliminary Injunction.

Dated: April 22, 2011

Respectfully Submitted,

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[13] NBI's source also says of saw palmetto: "[A] 2009 review of the research concluded that saw palmetto has not been shown to be more effective than placebo for" treating BPH symptoms, and a 2006 large study of men with moderate-to-sever BPH "found no improvement with 320 mg saw palmetto daily for 1 year versus placebo."